DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2956426

May 9, 2001

Mr. Gerritt J. Groeneweg, Owner
Groeneweg Dairy
10726 Avenue 19
Chowchilla, California 93610

WARNING LETTER

Dear Mr. Groeneweg:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 19, 2001, by FDA Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

On January 30, 2001, you consigned a cow (identified by USDA laboratory report number 406033) to be slaughtered for human food. USDA analysis of tissue samples collected from this cow identified the presence of the drug penicillin in the kidney at 0.64 parts per million (ppm), and in the liver at 0.19 ppm. The tolerance level for penicillin in the uncooked edible tissues of cattle is 0.05 ppm. Your use of penicillin in the animal resulted in the illegal drug residue found in the tissues. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The drug, AgriLabs brand of Agri-Cillin containing penicillin G procaine, that you use to treat your cows is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v), and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with approved labeling. Labeling directions for Agri-Cillin prescribe one mL per 100 pounds of bodyweight with no more than 10 mL administered to any given injection site. Your practice of administering one 30 mL injection at one site results in a dosage in excess of that allowed in the labeling. The label also warns against releasing animals for slaughter for food within ten days of use. Failure to document penicillin treatments is likely the cause of the illegal residues found in the animal you sold for food use.

Failure to comply with the label instructions presents the likely possibility that illegal residues will occur and makes the drug unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to

achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office, within fifteen (15) days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, US Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, Ca 94502.

Sincerely yours,

Dennis K. Linsley
District Director

cc: [redacted]